

UNBURN- lidocaine hydrochloride spray
Water-Jel Technologies

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Unburn Spray

Active ingredient

Lidocaine HCl 2.5%

Purpose

External analgesic

Uses

for the temporary relief of pain associated with:

- sunburn
- minor burns
- minor skin irritations
- insect bites

Warnings

For external use only

Do not use

- in large quantities, particularly over raw surfaces or blistered areas

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days
- condition clears up and occurs again within a few days

Keep out of the reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Other information

- store at 15 ° to 25 °C (59 ° to 77 °F)
- do not freeze
- you may report a serious adverse reaction to this product to 1-800-275-3433

Inactive ingredients

acrylates/C20-30 alkyl acrylate crosspolymer, aloe, caprylyl glycol, carbomer, chlorophenesin, edetate disodium, glyceryl-7 stearate, octoxynol-9, polysorbate 20, phenoxyethanol, purified water, spearmint oil, tea tree oil, trolamine, vitamin E acetate

1-800-275-3433info@waterjel.com www.waterjel.com

Principle Display Panel

COOLS & SOOTHES!

NEW!

WATERBASED
unburn[®]

SUNBURN RELIEF

Made By The Experts In Burn Care

**INSTANT PAIN RELIEF
PULLS THE HEAT
FROM THE BURN**

**NON-GREASY • QUICK DRYING
PAIN RELIEVING SPRAY GEL**

CONTAINS 2.5% LIDOCAINE

5 fl. oz. (150 mL)

UNBURN

lidocaine hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59898-510
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	
CAPRYLIC ALCOHOL (UNII: NV1779205D)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
SPEARMINT OIL (UNII: C3M81465G5)	
TEA TREE OIL (UNII: VIF565UC2G)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-510-45	150 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/01/2014	

Labeler - Water-Jel Technologies (155522589)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(59898-510)

Revised: 11/2017

Water-Jel Technologies